UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

ENDO PHARMACEUTICALS INC., Plaintiffs, v. ROXANE LABORATORIES, INC., Defendants.	C.A. No. 13-cv-3288-TPG
ENDO PHARMACEUTICALS INC. and GRÜNENTHAL GMBH, Plaintiffs, v. AMNEAL PHARMACEUTICALS, LLC and AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, Defendants.	C.A. No. 12-cv-8115-TPG
ENDO PHARMACEUTICALS INC. Plaintiffs, v. RANBAXY LABORATORIES LTD., RANBAXY INC. and RANBAXY PHARMACEUTICALS INC., Defendants.	C.A. No. 13-cv-8597-TPG

ENDO PHARMACEUTICALS INC. Plaintiffs, v. RANBAXY LABORATORIES LTD., RANBAXY INC. and RANBAXY PHARMACEUTICALS INC., Defendants.	C.A. No. 13-cv-4343-TPG

BRIEF IN SUPPORT OF DEFENDANTS' MOTION FOR REDUCTION IN THE NUMBER OF ASSERTED CLAIMS

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I. INTRODUCTION

Despite the impending close of fact discovery and commencement of expert discovery, and even though Plaintiff Endo Pharmaceuticals Inc. ("Endo") has had Defendant Roxane Laboratories, Inc.'s, Amneal Pharmaceutical LLC's, Ranbaxy Laboratories Ltd., Ranbaxy Inc.'s, and Ranbaxy Pharmaceuticals Inc.'s, (collectively "Defendants") Abbreviated New Drug Applications ("ANDA") for many months, Endo is still asserting at least 72 largely duplicative patent claims against Defendants from three patents[1]: claims 1-4, 16 and 18-20 of U.S. Patent No. 8,309,122 (Ex. A, "the '122 patent"), claims 1-2, 6, 12-14, 17, 21-44, 47, 49-51 and 54-82 of U.S. Patent No. 8,329,216 (Ex. B, "the '216 patent") and claim 4 of U.S. Patent No. 7,851,482[2] (Ex. C, "the '482 patent").

The Court has stated that the number of claims to be tried is to be reduced, and Endo acknowledges that it needs to reduce the number of claims to a manageable number before trial. (*See* Ex. F, July 24, 2014 Loeb Ltr. to Counsel, Proposed Case Management Order at 5-6; Ex. G, excerpt of Dec. 5, 2013 Tr. at 27:17-28:2.) There is no reason to wait until the eve of trial. Endo should reduce the number of asserted claims now—so the experts can draft their reports on the claims that are being asserted and will be tried before the Court. Endo has had more than sufficient time to review Defendants' respective ANDAs, Defendants' initial invalidity

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[1] U.S. Patent Nos. 8,114,383 ("the '383 patent"); 8,192,722 ("the '722 patent") and 8,309,060 ("the '060 patent") are not asserted against Roxane or the Ranbaxy defendants, but are asserted against other Defendants from co-pending actions. Plaintiffs asserted the '722 and '060 patents against Amneal, but the parties have entered into a stipulation of dismissal. Endo has asserted the '122, 216, and '482 patents against all parties in these litigations.

[2] Defendants do not request any particular limitation of claims in connection with the '482 patent in this motion as there is only one claim currently asserted by Endo. Nevertheless, Defendants have requested that Endo withdraw assertion of the '482 patent for numerous reasons. (*See* Ex. D, Jul. 16, 2014 D'Amore Ltr. to Loeb; Ex. E, Aug. 1, 2014 Cheek Ltr. to Loeb.)

contentions, and responses to Endo's interrogatories regarding Defendants' noninfringement contentions. To expect Defendants, in their expert reports, to address the volume of claims Endo is currently asserting is unreasonable, unmanageable, and a waste of time and resources for all parties and the Court.

Many of the asserted claims are directed to duplicative and overlapping subject matter. Any argument that Endo may make that the duplicative nature of the claims cuts toward no reduction because Defendants will have the same burden misses the point and is incorrect. Although the claims contain duplicative and overlapping subject matter, Defendants have the burden to prove each and every claim invalid by clear and convincing evidence. Because of the exacting standards for proving invalidity and because the overlapping subject matter is recited in each claim in a slightly different manner, Defendants are compelled to go through each and every claim, limitation by limitation, creating work that will prove unnecessary if the claims are going to be reduced before trial – and wasting time at trial.

Indeed, Endo's motion for a preliminary injunction against Roxane asserted only five claims from the '122 patent (claims 1, 2, 3, 16 and 18) and two claims from the '216 patent (claims 21 and 22). (*See* Ex. H, Endo's Motion for Preliminary Injunction at 10.) Endo also limited its discussion in its January 23, 2014 slide presentation for the Court to just four claims: claim 1 of the '122 patent and claims 1, 21, and 22 of the '216 patent. (*See* Ex. I, excerpt of Jan. 23, 2014 Endo Slides at 20-39.) In light of these actions, Endo's current refusal at this stage of the litigation to limit the case to fewer than 45 claims[3] against Defendants is unreasonable. (Ex.

[3] Until Endo filed its August 14, 2014 letter with the Court, Endo maintained that it would not limit the case to fewer than 60 claims before opening expert reports are due. Even a reduction to 45 claims would not be reasonable in view of the Court's and Defendants' desires to streamline the issues for trial.

F, Jul. 24, 2014 Loeb Ltr. to Counsel, Proposed Case Management Order at 5-6.)

When patentees assert unreasonably large numbers of patent claims, district courts routinely exercise their authority to limit the number of patent claims to be asserted in order to ensure that the Court and the parties are not buried in an endless litany of duplicative claims. *See In re Katz Interactive Call Processing Patent Litig.*, 639 F.3d 1303, 1312-13 (Fed. Cir. 2011) (affirming reduction of 1,975 asserted claims to 16 claims per defendant group). Defendants therefore respectfully request that the Court direct Endo to reduce its number of asserted claims from the '122 and '216 patents to no more than five per patent—and just the single remaining claim from the '482 patent—before the parties are required to prepare and serve opening expert reports.

II. FACTUAL BACKGROUND

A. Stage of the Proceedings

At the Court's request, Defendants presented examples of representative issues from their non-infringement and invalidity cases at two status conferences on February 20, 2014 and April 2, 2014. At the February 20 status conference, Defendants selected claim 20 of the '122 patent and claim 31 of the '216 patent as representative claims to discuss as examples of noninfringement issues for trial, indicating that they were still uncertain of which claims would actually be asserted against them. (Ex. J, Feb. 20, 2014 excerpt of Tr. at 67:21-68:7, 83:1-11.) Endo provided no indication at this status conference, which claims it would assert against the respective Defendants and did not discuss its infringement contentions related to any other claims.

At the April 2 status conference, Defendants again selected a representative claim, claim 19 from the '122 patent, to provide an example of invalidity issues for trial. (Ex. K, excerpt of Apr. 2, 2014 Tr. at 11:6-18.) Endo again failed to provide any indication which claims it would

assert at trial, despite Defendants' request to limit the asserted claims so that they could reduce the number of prior art references and limit issues for trial. (*Id.*)

At no time during or following the status conferences, did Endo give any notice to Defendants that it intended to limit Defendants to the exemplary arguments or references that were discussed at the status conferences.

In subsequent correspondence between the parties, Defendants maintained their position that Endo "withdraw duplicative claims so as to properly reduce the number of issues for trial," in response to Endo's improper assertion that Defendants would be limited to only the prior art invalidity defenses presented at the April 2, 2014 status conference. (Ex. L, May 15, 2014 Goodin Ltr. to Loeb at 1-2; Ex. M, May 28, 2014 Sudentas email to Loeb; Ex. N, Jun. 16, 2014 Sudentas email to Loeb.) Endo, however, continued its attempt to unilaterally limit Defendants' expert reports to only those specific issues identified during the February 20 and April 2 status conferences, but did not offer to limit the asserted claims or identify limitations that were not disputed as being within the prior art. (Ex. O, Jun. 17, 2014 Loeb Ltr. to Counsel at 6.)

In a letter dated July 24, Endo attached a Proposed Case Management Order that sought to limit both the number of Defendants' experts as well as the content of Defendants' expert reports, and provided an unreasonable proposed case schedule that Endo made up without conferring with Defendants on the dates. Endo proposed that the asserted claims would be limited to no more than 60 claims per defendant by August 4, 2014 and no more than 30 claims per defendant 20 days after the close of expert discovery. Endo did not provide any limitation on the content of its own expert reports. (Ex. F, July 24, 2014 Loeb Ltr. to Counsel, Proposed Case Management Order at 5-6.)

Roxane responded with a proposal that Endo first reduce the number of claims in this case to no more than ten total claims from the '122, '216, and '482 patents, and upon Endo's reduction of claims, Roxane would within 21 days limit its primary prior art references for each patent group—*i.e.*, the '122/'216 as one group and the '482 as the other. (Ex. P, Aug. 1, 2014 Sudentas Ltr. to Loeb at 1-2.) The prior art references, that were referred to in Roxane's August 1, 2014 letter are "primary" prior art references that Defendants intend to rely upon in order to show that the subject matter of the patent claims is disclosed by, or obvious in light of, the prior art. Defendants reserve the right to use other prior art references for a tutorial, to show the knowledge of a person of ordinary skill in the art, *see Randall Mfg. v. Rea*, 733 F.3d 1355, 1362-63 (Fed. Cir. 2013), and/or to satisfy other patent-law requirements, including, for example, enabling disclosure, reasonable expectation of success, and rebuttal of secondary considerations. Roxane also counter-proposed case deadlines and requested a meet and confer. (*Id.*) On August 1, Actavis, joined by other Defendants, sent a responsive letter to Endo in which it opposed the proposed limitations on Defendants' case, counter-proposed case deadlines, and requested a meet and confer. (See Ex. Q, Aug. 1, 2014, Yecies Ltr. to Loeb.)

On August 11, the parties met and conferred. Endo maintained that Defendants were limited to only the issues discussed at the February 20 and April 2 status conferences, but would not concede that Endo should then also be limited to the claims presented at those two status conferences. Although Endo admitted that the differences among the claims were not significant, Endo did not limit the number of asserted claims or identify any limitations that it would concede were present in the prior art. In other words, Endo's position was that Defendants' case should be strictly limited, but that there did not need to be any corresponding limitation on Endo's case.

Endo must have rethought the absurdity of its position because on August 14, 2014, Endo filed a letter and Proposed Case Management Order with the Court that did include a minor proposal to limit the asserted claims. (*See* D.I. 77, Ex. A at 6, filed in 13-cv-3288.) Endo agreed, for the first time, to reduce its asserted claims to 45 claims on August 29, 2014 and then to further reduce the asserted claims to 30 claims twenty days after the close of expert discovery, which would be January 1, 2015. (*Id.*) The two-step process and timing of Endo's proposed reductions, however, are not feasible; and the claim reduction is insufficient. While Endo's proposal provides a six-week period after reply expert reports for Endo to consider which claims it will assert, it provides less than two weeks between the time it intends to tell Defendants which claims it is asserting (January 1) and the time to be ready for trial (January 14). Endo cannot justify providing Defendants notice of which claims it will assert at trial less than two weeks before trial commences—especially when it contends that Defendants were required to limit their case to a few arguments presented in a few hours at status conferences that were held months before the close of fact discovery.

The parties are at an impasse, and Defendants now seek relief from the Court. Defendants have submitted contemporaneously with this motion a letter to the Court requesting that the Court order Endo to reduce the number of asserted claims against all Defendants to no more than a total of five claims from each of the patents-in-suit within three days following a case management conference with the Court. Based on Endo's agreement to limit the number of claims, Defendants' letter proposes that Defendants will then limit the primary prior art references used in their opening invalidity reports to a total of 20 primary references per patent group.

B. The Patents-in-Suit

As the Court may recall, Endo is asserting three patents against Roxane, Amneal, and

Ranbaxy in these cases—the '122, '216, and '482 patents. Appendix A contains a chart summarizing the 72 claims from the three patents that Endo is still asserting against Defendants in this case, *i.e.*, the '122, '216, '482 patents. The '122 and '216 patents share a common genealogy—both claim priority to a common provisional Application No. 60/303,357 ("the '357 application") filed July 6, 2001. (*See* Ex. A, the '122 patent; Ex. B, the '216 patent at "Related Applications.") Further, the patent applicants filed a terminal disclaimer for U.S. Application No. 11/680,432 ("the '432 application," which issued as the '122 patent) over U.S. Application No. 11/427,438 ("the '438 application," which issued as the '216 patent) disclaiming any term of the '122 patent that would extend beyond the term of the issued '216 patent due to the highly similar nature of the claims. (Ex. R, '432 application Terminal Disclaimer at 1.) The Examiner even noted in the Notice of Allowance for the '438 application:

> Instant claims 21-82 are similar to that of the claims of [the '432 application] and [I]nstant claims 1-20 are of narrower scope than that of [the '432 application]. Instant claims have been previously rejected over the same prior art that was also cited in [the '432 application]. However, Instant claims are found to be patentable in light of the [Board of Patent Appeals and Interferences] decision (dated 8/13/12) in the copending ['432 application].

(Ex. S, '438 application Notice of Allowance at 2.) The Examiner's statement highlights how similar the claims of the '122 and '216 patents are, as they were both rejected over the same prior art and allowed for the same reasons.

III. ARGUMENT

A. The Asserted Claims Are Highly Duplicative

There is an enormous amount of unnecessary duplication in the patent claims that Endo insists on maintaining. Requiring experts to address each of these duplicative, overlapping claims limitation by limitation, as Defendants would need to do, would serve no purpose but to waste the time and resources of the parties, and ultimately of the Court. *See In re Brimonidine*

Patent Litig., 643 F.3d 1366, 1372, 1386 (Fed. Cir. 2011) (finding that Apotex failed to prove invalidity of the asserted claims where it did not argue its case on a claim-by-claim basis and failed to demonstrate that all of the 69 asserted claims were invalid and further holding that the district court did not abuse its discretion in refusing to consider obviousness arguments in light of the absence of supporting expert testimony). The following examples illustrate the duplicative nature of the asserted claims:

The '122 patent:

Endo asserts eight claims from the '122 patent, all of which cover largely overlapping subject matter calling for a controlled-release oxymorphone tablet with specified dissolution profiles. For example, independent claims 1 and 19 cover a controlled-release oxymorphone tablet with a dissolution profile where about 15% to about 50% by weight of the oxymorphone is released from the tablet at about 1 hour in the test. Claim 19, however, also provides dissolution ranges for the same tablet at hour 4 and hour 10—the same ranges as described in dependent claims 2 and 3—and the requirement that the tablet comprises a hydrophilic material—the same hydrophilic material described in dependent claim 4. As illustrated below, there is substantial overlap between Endo's assertion of claims 1-4 and its assertion of claim 19 (the various colors indicate the duplicative nature of the claims):

Claims 1-4	**Claim 19**
1. An analgesically effective controlled release pharmaceutical composition with a twelve hour dosing interval in the form of a tablet,	19. An analgesically effective controlled release pharmaceutical composition with a twelve hour dosing interval in the form of a tablet,
comprising oxymorphone or a pharmaceutically acceptable salt thereof as the sole active ingredient in the tablet, and a controlled release delivery system comprising at least one pharmaceutical excipient,	comprising oxymorphone or pharmaceutically acceptable salt thereof as the sole active ingredient in the tablet and a controlled release delivery system comprising a hydrophilic material that forms a gel upon exposure to gastrointestinal fluid,

[4. The pharmaceutical composition of claim 1 wherein the controlled release delivery system comprises a hydrophilic material that forms a gel upon exposure to gastrointestinal fluid.]	
wherein upon placement of the composition in an in vitro dissolution test comprising USP Paddle Method at 50 rpm in 500 ml media having a pH of 1.2 to 6.8 at 37° C., about 15% to about 50%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 1 hour in the test.	wherein upon placement of the composition in an in vitro dissolution test comprising USP Paddle Method at 50 rpm in 500 ml media having a pH of 1.2 to 6.8 at 37° C., about 15% to about 50%, by weight, of the oxymorphone or salt thereof is released from the composition at about 1 hour in the test,
2. The pharmaceutical composition of claim 1 wherein about 45% to about 80%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 4 hours in the test.	about 45% to about 80%, by weight, of the oxymorphone or salt thereof is released from the composition at about 4 hours in the test,
3. The pharmaceutical composition of claim 1 wherein at least about 80%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 10 hours in the test.	and at least about 80%, by weight, of the oxymorphone or salt thereof is released from the composition at about 10 hours in the test.

The ‘216 patent:

Endo asserts 63 claims from the ‘216 patent. These claims, like those of the ‘122 patent, are directed to controlled-release formulations of oxymorphone, and many of the claims repeat dissolution profile limitations that are contained in the ‘122 patent claims. For example, claims 13 and 21 of the ‘216 patent are not only highly redundant of each other, but also describe an oxymorphone tablet with the same dissolution profile already described for the oxymorphone tablet of claim 1 of the ‘122 patent (the various colors indicate the duplicative nature of the claims):

Claim 13	**Claim 21**
A pharmaceutical tablet prepared by:	A pharmaceutical tablet prepared by:
a. mixing oxymorphone or a pharmaceutically acceptable salt of oxymorphone and controlled release granules comprising a hydrophilic material and one or more optional excipients; and	a. mixing oxymorphone or a pharmaceutically acceptable salt of oxymorphone and one or more controlled release excipients; and

b. directly compressing the mixture of (a) to form the tablet,	b. forming the tablet,
wherein upon placement of the tablet in an in vitro dissolution test comprising USP Paddle Method at 50 rpm in 500 ml media having a pH of 1.2 to 6.8 at 37° C., about 15% to about 50%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 1 hour in the test.	wherein upon placement of the tablet in an in vitro dissolution test comprising USP Paddle Method at 50 rpm in 500 ml media having a pH of 1.2 to 6.8 at 37° C., about 15% to about 50%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 1 hour in the test; and wherein upon oral administration to a human subject the tablet alleviates pain for 12 to 24 hours.

These redundancies are just compounded by, for example, claims 23-30, which depend from claim 21 and which go on to add time points at hours 1, 2, 3, 5, 6, 8, and 10 to the disclosed dissolution profile:

Claim 23	**Claims 24-30**
23. The tablet of claim 21 wherein at least 27%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 1 hour in the test,	24. The tablet of claim 21, wherein at least 27%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 1 hour in the test.
at least 40%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 2 hours in the test,	25. The tablet of claim 21, wherein at least 40%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 2 hours in the test.
at least 50%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 3 hours in the test,	26. The tablet of claim 21, wherein at least 50%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 3 hours in the test.
at least 64%, , by weight, of the oxymorphone or salt thereof is released from the tablet at about 5 hours in the test,	27. The tablet of claim 21, wherein at least 64%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 5 hours in the test.
at least 70%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 6 hours in the test,	28. The tablet of claim 21, wherein at least 70%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 6 hours in the test.

	29. The tablet of claim 21, wherein at least 79%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 8 hours in the test.
at least 85%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 10 hours in the test,	30. The tablet of claim 21, wherein at least 85%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 10 hours in the test.
and at least 89%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 12 hours in the test.	

Other asserted independent claims from the '216 patent are equally duplicative. For example, the only difference between claims 31 and 38 (underlined below) is that the latter provides dissolution ranges at hours 4 and 10—the same range at hours 4 and 10 already provided in other asserted claims, *e.g.* claims 2, 3 and 19 of the '122 patent and claims 22, 54, 71, 73, 74 and 77 of the '216 patent:

Claim 31	**Claim 38**
A method for treating pain in a human subject in need of acute or chronic pain relief, comprising the steps of:	A method for treating pain in a human subject in need of acute or chronic pain relief, comprising the steps of:
(a) Providing a solid oral dosage form of a controlled release oxymorphone formulation with a release rate profile designed to provide adequate blood plasma levels over at least 12 hours to provide sustained pain relief over this same period comprising about 5 mg to about 80 mg oxymorphone or a pharmaceutically acceptable salt thereof wherein oxymorphone is the sole active ingredient, and wherein upon placement of the composition in an in vitro dissolution test comprising USP Paddle Method at 50 rpm in 500 ml media having a pH of 1.2 to 6.8 at 37° C., about 15% to about 50%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 1 hour in the test; and	(a) Providing a solid oral dosage form comprising about 5 mg to about 80 mg oxymorphone or a pharmaceutically acceptable salt thereof in a controlled release delivery system with a release rate profile designed to provide adequate blood plasma levels over at least 12 hours to provide sustained pain relief over this same period, wherein oxymorphone is the sole active ingredient, and wherein upon placement of the composition in an in vitro dissolution test comprising USP Paddle Method at 50 rpm in 500 ml media having a pH of 1.2 to 6.8 at 37° C., about 15% to about 50%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 1 hour in the test,

	about 45% to about 80%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 4 hours in the test, and at least about 80%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 10 hours in the test; and
(b) administering a single dose of the dosage form to the subject,	(b) administering a single dose of the dosage form to the subject,
wherein the oxymorphone C_{max} is at least 50% higher when the dosage form is administered to the subject under fed as compared to fasted conditions.	wherein the oxymorphone C_{max} is at least 50% higher when the dosage form is administered to the subject under fed versus fasted conditions.

Again, the duplicative nature of these claims is only multiplied by the fact that Endo is asserting claims depending from claims 31 and 38 with identical limitations:

Claims depending from claim 31	**Claims depending from claim 38**
35. The method of claim 31 wherein the difference in the oxymorphone area under the curve (AUC(0-inf) between fed and fasted conditions is less than 20%.	40. The method of claim 38 wherein the difference in the oxymorphone area under the curve AUC(0-inf) between fed and fasted conditions is less than 20%.
36. The method of claim 35 wherein the difference in AUC(0-inf) between fed and fasted conditions is about 18%.	41. The method of claim 40 wherein the difference in AUC(0-inf) between fed and fasted conditions is about 18%.
37. The method of claim 31 wherein upon oral administration of the dosage form to the subject under fed or fasting conditions: (i) the dosage form provides detectable blood plasma levels of 6-OH oxymorphone and oxymorphone; (ii) the blood plasma levels of 6-OH oxymorphone and oxymorphone peak within about 1 hour to about 8 hours after administration; and (iii) the blood plasma levels of 6-OH oxymorphone and oxymorphone exhibit a ratio of AUC(0-inf) of blood plasma level versus time for 6-OH oxymorphone compared to oxymorphone in a range of about 0.5 to about 1.5.	42. The method of claim 38 wherein upon oral administration of the dosage form to the subject under fed or fasting conditions: (i) the dosage form provides detectable blood plasma levels of 6-OH oxymorphone and oxymorphone; (ii) the blood plasma levels of 6-OH oxymorphone and oxymorphone peak within about 1 hour to about 8 hours after administration; and (iii) the blood plasma levels of 6-OH oxymorphone and oxymorphone exhibit a ratio of AUC(0-inf) of blood plasma level versus time for 6-OH oxymorphone compared to oxymorphone in a range of about 0.5 to about 1.5.

Independent claims 49 and 66 are also highly duplicative. The only limitations that differ between these claims (underlined below) are also present in numerous other claims across the '216 patent:

- the limitation from claim 49 that "the oxymorphone C_{max} is at least 50% higher when the dose [dosage form] is administered to the subject under fed as compared to fasted conditions" is common to at least claims 31-44, 47, 49-51, 54, and 56.

- the limitation from claim 66 that "the blood plasma levels of oxymorphone comprise one or more peaks" is common to at least claims 66 and 68-71.

Claim 49	**Claim 66**
An analgesically effective controlled release pharmaceutical composition for oral delivery, comprising:	An analgesically effective controlled release pharmaceutical composition for oral delivery, comprising:
a. a controlled release delivery system with a release rate profile designed to provide adequate blood plasma levels over at least 12 hours to provide sustained pain relief over this same period; and	a. a controlled release delivery system with a release rate profile designed to provide adequate blood plasma levels over at least 12 hours to provide sustained pain relief over this same period; and
b. about 5 mg to about 80 mg of oxymorphone or a pharmaceutically acceptable salt of oxymorphone, wherein oxymorphone is the sole active ingredient,	b. about 5 mg to about 80 mg of oxymorphone or a pharmaceutically acceptable salt of oxymorphone, wherein oxymorphone is the sole active ingredient,
wherein upon oral administration of a single dose of the composition to a human subject, the oxymorphone C_{max} is at least 50% higher when the dose is administered to the subject under fed as compared to fasted conditions, and wherein upon placement of the composition in an in vitro dissolution test comprising USP Paddle Method at 50 rpm in 500 ml media having a pH of 1.2 to 6.8 at 37° C., about 15% to about 50%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 1 hour in the test.	wherein upon placement of the composition in an in vitro dissolution test comprising USP Paddle Method at 50 rpm in 500 ml media having a pH of 1.2 to 6.8 at 37° C., about 15% to about 50%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 1 hour in the test, and wherein upon oral administration of the composition to a human subject, the blood plasma levels of oxymorphone comprise one or more peaks.

Not only are the claims redundant, but the limitations themselves repeat in a variety of combinations across the 63 asserted claims. Take claim 1 for example, each of its limitations

repeats in at least five claims, with one limitation appearing in over forty claims:

1. An oral controlled release oxymorphone formulation, comprising:	
a. about 5 mg to about 80 mg of oxymorphone or a pharmaceutically acceptable salt of oxymorphone; and	Claims 1, 2, 6, 31-44, 47, 49-51, 54-71, 81-82
b. a hydrophilic material,	Claim 1, 2, 6, 13-14, 17, 43-44, 47
wherein upon oral administration of the formulation to a subject in need of an analgesic effect:	
(i) the formulation provides detectable blood plasma levels of 6-OH oxymorphone and oxymorphone;	Claims 1, 2, 6, 37, 42, 68, 76, 78
(ii) the blood plasma levels of 6-OH oxymorphone and oxymorphone peak within about 1 hour to about 8 hours after administration;	Claims 1, 2, 6, 37, 42, 68, 76, 78
(iii) the blood plasma levels of 6-OH oxymorphone and oxymorphone exhibit a ratio of area under the curve (AUC(0 to inf)) of blood plasma level versus time for 6-OH oxymorphone compared to oxymorphone in a range of about 0.5 to about 1.5;	Claims 1, 2, 6, 37, 42, 68, 76, 78
(iv) the duration of the analgesic effect is through at least about 12 hours after administration; and	Claims 1, 2, 6, 76, 78
	Similar limitations also appear in: Claims 31-44, 47, 49-51, 54, 66-71 (“designed to provide adequate blood plasma levels over at least 12 hours to provide sustained pain relief over this same period”)
(v) the blood plasma levels of oxymorphone exhibit two or three peaks within about 12 hours after administration.	Claim 1, 2, 6, 69, 78
	Similar limitations also appear in: Claim 66, 68-71 (“the blood plasma levels of oxymorphone comprise one or more peaks”) Claim 67 (“wherein the blood plasma levels comprise two peaks.”)

As illustrated above, the claims currently asserted by Endo are overlapping but with

minor differences that makes it next to impossible to map how they intersect, let alone address them efficiently in an expert report. Only by engaging in the unnecessary and time-consuming task of addressing each claim individually, reiterating the same analysis for each repeating limitation, can Defendants be sure to address every possible combination of limitations in the claims asserted by Endo. Federal Circuit law holds that a defendant seeking to invalidate claims in a patent has the burden to specifically address each and every claim it is seeking to invalidate. *In re Brimonidine*, 643 F.3d at 1372, 1376. This burden will then be forced upon the Court when it comes to trying all of these duplicative claims.

B. The Court Should Exercise Its Inherent Authority To Manage Its Docket By Limiting The Number of Asserted Claims

A district court has broad inherent powers to manage its cases. *See, e.g., Dumann Realty, LLC v. Faust*, 2011 WL 2749523 at *2 (S.D.N.Y. July 8, 2011) ("[C]ourts have inherent power to manage and control their dockets effectively and to provide for timely disposition of cases."); *Alghanim v. Alghanim*, 828 F. Supp. 2d 636, 664 (S.D.N.Y. 2011) (exercising court's inherent power to manage its docket in order to stay pending nonarbitrable claims); *Spray Holdings, Ltd. v. Pali Fin. Grp., Inc.*, 269 F. Supp. 2d 356, 366 (S.D.N.Y. 2003) (district courts possess "the power inherent in every court to control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants") (internal citation omitted). These powers include the authority to limit the number of patent claims parties may assert. *In re Katz*, 639 F.3d at 1312-13.

The Federal Circuit has addressed claim reduction by district courts in at least three cases and affirmed the reduction of claims in all of them. *See id.* (reduction of 1,975 claims to 16 claims per defendant group); *Stamps.com Inc. v. Endica, Inc.*, 437 Fed. Appx. 897, 902-03 (Fed. Cir. 2011) (reduction of 629 claims to 15 claims for 8 patents); *ReRoof Am., Inc. v. United*

Structures of Am., Inc., 215 F.3d 1351 (Fed. Cir. 1999) (reduction of 18 claims to 5 claims for 5 patents for trial). Other district courts also have routinely ordered patentees to reduce their number of asserted claims. *See, e.g.*, *Havco Wood Prods., LLC. v. Industrial Hardwood Prods., Inc.,* No. 10-cv-566-WMC, 2011 U.S. Dist. LEXIS 130757, *16-18 (W.D. Wis. Nov. 10, 2011) (limiting asserted patent claims from 135 to 15 for 5 patents in light of upcoming expert discovery); *Adobe Sys. v. Wowza Media Sys. LLC*, 2013 U.S. Dist. LEXIS 65049 (N.D. Cal. May 6, 2013) (ordering Plaintiff "to limit its asserted claims in this action to twenty representative claims" for 4 patents); *High Point Sarl v. Sprint Nextel Corp.*, 2010 U.S. Dist. LEXIS 85497 (D. Kan. Aug. 18, 2010) (ordering Plaintiff to reduce the number of asserted claims from 178 claims to 20 claims for 4 patents); *Masimo Corp. v. Philips Elecs. N. Am. Corp.*, 918 F. Supp. 2d 277, 282 (D. Del. 2013) (reduction of 95 claims to 30 claims for 7 patents); *Fenster Family Patent Holdings, Inc. v. Siemens Med. Solutions*, No. 04-0038-JJF, 2005 U.S. Dist. LEXIS 20788, at *8 (D. Del. Sep. 20, 2005) (reduction of 90 claims to 10 claims for 8 patents).

The Federal Circuit's opinion in the *Katz* case is instructive. In *Katz*, the court held that it was not a violation of the Plaintiff's due process rights for the district court to limit the number of claims the Plaintiff could assert. *In re Katz*, 639 F.3d at 1312. The court concluded that in light of the many examples of duplicative claims in the asserted patents, "it was both efficient and fair" for the district court to require the Plaintiff to show that the unselected claims raised unique questions of validity or infringement. *Id.* "While different claims are presumed to be of different scope, that does not mean that they necessarily present different questions of validity or infringement." *Id.* at 1313.

The same analysis applies here. As discussed above, the '122 and '216 patents share a common genealogy (as well as numerous claim limitations). In fact, here as in *Katz,* there is a

terminal disclaimer that was filed in the application for the '122 patent disclaiming the application for the '216 patent. The examiner even noted the patent claims' similarity in the notice of allowance of the '216 patent stating the claims of both patents were rejected over the same prior art and allowed for the same reasons. (*See* Ex. S, '438 application Notice of Allowance at 2.)

As shown in the many examples above, Endo's asserted claims are rife with duplication. Endo has not shown and cannot show that every one of the duplicative claims presents unique and separate issues of validity and/or infringement requiring them all to be tried. Endo has already demonstrated that it can limit the number of asserted claims—it did so in its preliminary injunction motion and its slide presentation at the January 23 status conference. If Endo can limit itself to asserting eight claims in seeking a preliminary injunction, there is no reason that Endo cannot do the same now for trial. Arguably, those eight claims are the claims that Endo felt were representative of all of the duplicative claims of the '122 and '216 patents.

It is both efficient and fair for the Court to exercise its authority to require Endo to reduce its number of asserted claims to no more than five claims from each of the '122, '216 and '482 patents and streamline the case before the parties incur the unnecessary burden of addressing all claims currently asserted.

IV. CONCLUSION

The Court need not and should not allow Endo to waste time and resources by presenting a massive set of duplicative and overlapping claims. In exercising its inherent authority to manage its docket, the Court can and should require Endo to reduce its number of asserted claims to a manageable number that can realistically be addressed in the upcoming opening expert reports. Defendants respectfully request that the Court order Endo to limit the number of asserted claims to five or fewer per each of the '122, '216 and '482 patents.

Dated: August 28, 2014

Respectfully submitted,

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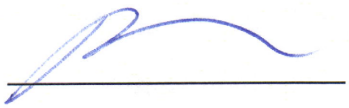

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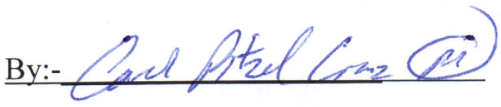
By:- 

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